JUL 2 5 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

K021330

1-1 Device Name:	Magnetic Resonance Diagnostic Device
1-2 Proprietary Name:	Magnetom Trio Head Coil
1-3 Classification:	Class II
1-4 Establishment Registration	1529041
1-5 Manufacture Facility Location	USA Instruments, 1515 Danner Drive Aurora, Ohio 44202 USA Telephone: 330-562-1000; Fax: 330-562-1422
1-6 Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
1-7 Intended Use:	The Magnetom Trio Head Coil is a quadrature transmit receive coil used for obtaining diagnostic images of the head at the 3.0Tesla field strength in Magnetic Resonance Imaging. The indications for use are the same as for standard MR imaging. The Magnetom Trio Head Coil is designed for use with the Siemens Magnetom Trio 3.0Tesla MRI Scanner.
1-8 Device Description:	The Magnetom Trio Head Coil is a 16 z-element quadrature transmit receive coil. The coil elements and associated circuitry are enclosed to prevent any exposure to patient or environment. The coil electronics are enclosed in a rigid former. The former is a split top design with latching device and a large open viewing window on the top. The coil design facilitates the scanning of patients with different head sizes and maximizes patient comfort and ease of use.

1-9 Safety and Effectiveness:

Magnetom Trio Head Coil	Comparison to Predicate or other 510(k) cleared products
Intended Use: Head Imaging including diffusion weighted imaging, angiography, functional MRI, CSI imaging, and 3D TOF imaging.	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)
Indications for Use: Identical to routine MRI imaging	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)
Coil Enclosure Material: Polyurethane Plastic, Vinyl coated Foam	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)
Coil Design: 16 z-element transmit receive Quadrature design	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)
Decoupling: Actively switched PIN diodes during transmit and receive mode	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)
Prevention of RF Burns: The coil's transmit/receive switch uses pin diodes to isolate the receive channel from the transmit channel; coil elements and circuitry are enclosed in a non-conductive housing	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)
Radio Frequency Absorption: Power deposition during imaging is limited by SAR algorithm	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)
Formation of Resonance Loops: Active diodes and fast RF blowing fuses isolate the coil elements from RF fields; length of cable and stiffness does not permit looping	-Similar to the Allegra 3.0Tesla Tx/Rx Head Coil manufactured by USA Instruments, Inc. (K002179)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2002

Ms. Christie Shumaker
Manager QA and Regulatory
USA Instruments, Inc.
1515 Danner Drive
AURORA OH 44202

Re: K021330
Trade/Device Name: Magnetom Trio Quadrature Tx/Rx Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: April 24, 2002
Received: April 26, 2002

Dear Ms. Shumaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021330

Device Name: Magnetom Trio Head Coil

Indications for Use: The Magnetom Trio Head Coil is designed to provide Magnetic Resonance Images of the brain, cervical spine, soft tissues and vasculature of the head, neck and upper chest. The Magnetom Trio Head Coil is designed for use with the Magnetom Trio 3.0Tesla scanner manufactured by Siemens Medical Systems.

Anatomic Regions: Soft tissues and vasculature of the head, neck and upper chest.
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The 3.0Tesla MRI system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

David G. Burgess

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021330